

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 25, 2020

Findings Date: February 25, 2020

Project Analyst: Ena Lightbourne

Team Leader: Lisa Pittman

Project ID #: B-11831-19

Facility: Arden Dialysis

FID #: 150248

County: Buncombe

Applicant(s): Total Renal Care of North Carolina, LLC

Project: Change of scope and cost overrun for Project ID# B-11037-15 (Develop a new dialysis facility by relocating 10 stations from Swannanoa Dialysis Center to Arden Dialysis) to relocate no more than four dialysis stations from Asheville Kidney Center to Arden Dialysis pursuant to Policy ESRD-2, for a total of no more than 14 stations upon completion of this project and Project ID# B-11037-15

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

The applicant, Total Renal Care of North Carolina, LLC, referred to hereinafter as “the applicant” proposes a change of scope and cost overrun for Project ID# B-11037-15 (Develop a new dialysis facility by relocating 10 stations from Swannanoa Dialysis Center to Arden Dialysis) to relocate no more than four dialysis stations from Asheville Kidney Center to Arden Dialysis pursuant to Policy ESRD-2, for a total of no more than 14 stations upon completion of this project and Project ID# B-11037-15.

A certificate of need was issued September 29, 2015 for Project B-11037-15, (Develop a new dialysis facility by relocating 10 stations from Swannanoa Dialysis Center to Arden Dialysis) This application is a change of scope to relocate four dialysis stations from Asheville Kidney Center to Arden Dialysis for a total of no more than 14 stations upon completion of this project and Project ID# B-11037-15. This application includes a cost-overrun of \$641,681 which results in a total combined capital cost of \$1,914,206. In Section F, page 34, the applicant states that the cost overrun is due to the construction costs at the new site and the furniture, fixtures and equipment for the additional stations. In Exhibit C-9, the applicant provides a Material Compliance approval letter dated July 31, 2018 for the change of site for Project ID# B-11037-15.

Need Determination

There were no need determinations in the 2015 State Medical Facilities Plan (SMFP) applicable to Project ID# B-11037-15 and the applicant proposes no changes in the current application which would affect that determination. The applicant does not propose to increase the number of licensed beds in any category, add any new health services, or acquire equipment for which there is a need determination in the 2019 SMFP. Therefore, there are no need determinations applicable to this review.

Policies

Project ID# B-11037-15 was found to be consistent with Policy ESRD-2 as published in the 2015 SMFP. The applicant proposes no changes in the current application which would affect that determination. There are no policies in the 2019 SMFP that are applicable to this review.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

The applicant proposes a change of scope and cost overrun for Project ID# B-11037-15 (Develop a new dialysis facility by relocating 10 stations from Swannanoa Dialysis Center to Arden Dialysis) to relocate no more than 4 dialysis stations from Asheville Kidney Center to Arden Dialysis pursuant to Policy ESRD-2, for a total of no more than 14 stations upon completion of this project and Project ID# B-11037-15.

A certificate of need was issued September 29, 2015 for Project B-11037-15, (Develop a new dialysis facility by relocating 10 stations from Swannanoa Dialysis Center to Arden Dialysis) This application is a change of scope to relocate four dialysis stations from Asheville Kidney Center to Arden Dialysis for a total of no more than 14 stations upon completion of this project and Project ID# B-11037-15. This application includes a cost-overrun of \$641,681 which results in a total combined capital cost of \$1,914,206.

The following tables, summarized from Section A.4, page 7, of the application, show the Arden Dialysis facility, and the Asheville Kidney Center facility from which the applicant plans to relocate four stations.

Arden Dialysis		
Stations	Description	Project ID #
0	Total # existing certified stations as reported in the SDR in effect on the day the review begins	
+4	# of stations to be added as part of this project	
10	# of stations previously approved to be added but not yet certified	B-11037-15
14	Total # of stations upon completion of all facility projects	

Asheville Kidney Center		
Stations	Description	Project ID #
52	Total #existing certified stations as reported in the SDR in effect on the day the review begins	
-4	# of stations to be deleted as part of this project	B-11831-19
48	Total # of stations upon completion of all facility projects	

As shown in the table above, upon project completion, Arden Dialysis will be certified for 14 dialysis stations, and Asheville Kidney Center will be certified for 48 dialysis stations.

Patient Origin

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Thus, the service area for this facility consists of Buncombe County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates projected patient origin. In Section C, page 18, the applicant states that the proposed project is for a new facility with no historical patient data.

County	Second Full FY of Operation 1/1/2022-12/31/2022	
	# of In-Center Patients	% of Total
Buncombe	42	93.3%
Henderson	3	6.7%
Total	45	100.0%

Source: Section C.3, page 19

In Section C, pages 19-20, the applicant provides the assumptions and methodology used to project its patient origin. The applicant states:

“The previous approved application included 32 letters of support from in-center dialysis patients, including 30 from patients living in Buncombe County and 2 from patients living in Henderson County... It was determined that DaVita is serving a total of at least 13 additional in-center patients at Asheville Kidney Center and Hendersonville Dialysis, who live near the southern part of Buncombe County and who are not patients at these facilities when the previously approved application was submitted.

...

These letters, in addition to the letters from the previously approved application, document the projected patient origin.”

The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant assumes that the 32 patients who signed letters of support in the previous application will transfer to the new facility.
- The applicant uses patients currently dialyzing at DaVita-owned facilities, Asheville Kidney Center in Buncombe County and Hendersonville Dialysis in Henderson, to project patient origin.
- The applicant assumes that the 13 additional patients that began dialyzing at Asheville Kidney Center and Hendersonville Dialysis after the submission of the previous application will transfer to the new facility. Exhibit C-3 contains copies of the patients’ letters of support.

Analysis of Need

In Section C, page 21, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 21, the applicant states that during the development of project B-11037-15, DaVita served an additional 13 patients in Buncombe

County. These patients have stated that it would be more convenient having their dialysis services at the new facility. The applicant states that the additional stations are needed to meet the need of the additional in-center patients.

The information is reasonable and adequately supported based on the following:

The applicant begins the projections for Arden Dialysis by using the 32 patients from Buncombe County who have signed letters of support for the previously approved project and adds 13 additional patients from Buncombe County who have signed letters of support and who were not patients when the original application was submitted.

Projected Utilization

In Section C, the applicant provides the assumptions and methodology used to project utilization, which is summarize below:

- The applicant begins with the approved 10 stations and adds the four proposed stations from Asheville Kidney Center.
- The applicant uses the Buncombe County Five Year Average Annual Change Rate (AACR) of 0.3 percent to project utilization in the future years.
- The applicant identifies three existing patients living in Henderson County and adds them to the facility's census.
- Operating Year 1 (OY1) = January 1 through December 31, 2021 (CY2021).
Operating Year 2 (OY2) = January 1 through December 31, 2022 (CY2022)

In Section C, page 21 and Section Q, the applicant provides projected utilization, as illustrated in the following table.

Arden Dialysis	IC Stations	IC Patients
<p>Arden Dialysis begins with the 32 patients who have signed letters of support for the previously approved project and adds 13 additional patients who have signed letters of support.</p> <p>Arden Dialysis begins with the 10 stations from the previously approved project and adds 4 stations relocated from Asheville Kidney Center.</p> <p>This is the station count and census as of 01/01/2021</p>	$10 + 4 = 14$	$32 + 13 = 45$
<p>The facility's Buncombe County patient census projected forward a year to 12/31/2021 and is increased by the Five-Year AACR of 0.3 percent for Buncombe County.</p>		$42 \times 1.003 = 42.126$
<p>The 3 patients from outside Buncombe County are added to facility's census. This the ending census as of 12/13/2021 (OY1).</p>		$42.126 + 3 = 45.123$
<p>The facility's Buncombe County patient census is projected forward a year to 12/31/2022 and is increased by the Five-Year AACR of 0.3 percent for Buncombe County.</p>		$42.126 \times 1.003 = 42.252$
<p>The 22 patients from outside Buncombe County are added to the facility's census. This the ending census as of 12/13/2022 (OY2).</p>	14	$42.252 + 3 = 45.252$

The applicant projects to serve 45 in-center patients in OY1 and 45 in-center patients in OY2. Thus, the applicant projects that Arden Dialysis will have a utilization rate of 80.4% or 3.214 patients per station per week ($45 \text{ patients} / 14 \text{ stations} = 3.214 / 4 = 0.8036$ or 80.4%) in OY1. The projected utilization of 3.214 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization is reasonable and adequately supported based on the following:

- The applicant begins its projections with the 45 patients from Asheville Kidney Center and Hendersonville Dialysis who have signed letters of support and stated their intention to transfer their dialysis services to Arden Dialysis.
- The applicant projects that the Buncombe County patient census at Arden Dialysis will increase by the Buncombe County AACR of 0.3 percent, as reported in the July 2019 SDR.
- The utilization rate by the end of OY1 is above the minimum standard of 3.2 patient per station per week.

Access

In Section C, page 23, the applicant states:

“By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.

We will make every reasonable effort to accommodate all patients, especially those with special needs such as the handicapped, patients attending school or patients who work. Dialysis services will be provided six days per week with two patient shifts per day to accommodate patient need.

Arden Dialysis will help uninsured/underinsured patients with identifying and applying for financial assistance; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”

In Section L, page 47, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Arden Dialysis Payor Category	In-Center Dialysis	
	# of Patients	% of Total
Self-Pay	0.0	0.0%
Insurance**	3.8	8.4%
Medicare**	33.4	74.3%
Medicaid**	3.2	7.2%
Other (VA)	4.6	10.2%
Total	45.0	100.0%

Source: Section L, page 47

**Including any manage care plans

The projected payor mix is reasonable and adequately supported based on the following:

- The applicant’s projected payor mix is based on the patient payments that have been received in the last full operating year at the facilities that are losing stations.
- The applicant projects that patients at Asheville Kidney Center will transfer their dialysis services to Arden Dialysis based on the letters of support received in this application and the previously approved application.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
 - The applicant adequately explains why the population to be served needs the services proposed in this application.
 - Projected utilization is reasonable and adequately supported.
 - The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.
- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes a change of scope and cost overrun for Project ID# B-11037-15 (Develop a new dialysis facility by relocating 10 stations from Swannanoa Dialysis Center to Arden Dialysis) to relocate no more than 4 dialysis stations from Asheville Kidney Center to Arden Dialysis pursuant to Policy ESRD-2, for a total of no more than 14 stations upon completion of this project and Project ID# B-11037-15.

In Section D, page 27, the applicant states that four stations will be relocated from Asheville Kidney Center to Arden Dialysis.

In Section D, pages 27-29, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced, eliminated or relocated will be adequately met following completion of the project. On page 28, the applicant states:

“Given this projected growth of the in-center patient population, the need of the facility’s patients will continue to be met. Additional Certificate of Need applications will be submitted based on facility need as the facility approaches full capacity.”

In Section D, page 28, the applicant provides projected utilization for Asheville Kidney Center, as illustrated in the following table.

Asheville Kidney Center	In-Center Stations	In-Center Patients
Asheville Kidney Center begins with 166 patients on 52 stations as of 1/1/2019	52	166
The facility's Buncombe County patient census projected forward a year to 12/31/2019 and is increased by the Five-Year AACR of 0.3 percent for Buncombe County.		$157 \times 1.003 = 157.471$
The 9 patients from outside Buncombe County are added to facility's census. This the ending census as of 12/13/2019		$157.471 + 9 = 166.47$
The facility's Buncombe County patient census is projected forward a year to 12/31/2020 and is increased by the Five-Year AACR of 0.3 percent for Buncombe County.		$157.471 \times 1.003 = 157.943$
The 9 patients from outside Buncombe County are added to the facility's census. This the ending census as of 12/13/2020.		$157.943 + 9 = 166.94$
Arden Dialysis is projected to be certified on 1/1/2021 <ul style="list-style-type: none"> • Four stations are projected to transfer to Arden Dialysis from Asheville Kidney Center. • Thirty-nine Buncombe county patients are projected to transfer to Arden Dialysis from Asheville Kidney Center. This the census for Buncombe County patients as of 1/1/2021 	$52 - 4 = 48$	$157.943 - 39 = 118.943$
This is the station count and in-center census on 1/ 1/2021	48	$118 + 9 = 127$
The facility's Buncombe County patient census projected forward a year to 12/31/2021 and is increased by the Five-Year AACR of 0.3 percent for Buncombe County.		$118 \times 1.003 = 118.354$
Nine patients from outside Buncombe County are added to facility's census. This is the ending census as of the end of OY1.		$118.354 + 9 = 127.35$
The facility's Buncombe County patient census projected forward a year to 12/31/2022 and is increased by the Five-Year AACR of 0.3 percent for Buncombe County.		$118.354 \times 1.003 = 118.709$
The 9 patients from outside Buncombe County are added to the facility's census. This is the ending census as of the end of OY2.		$118.7091 + 9 = 127.71$

Source: Section D, page 28

In Section D, page 28, the applicant projects that by the end of OY1, Asheville Kidney Center is projected to have 127 in-center patients for a utilization of 66.15% or 2.64 patients per station, per week. This is based on 127 in-center patients dialyzing on 48 certified stations ($127 / 48 = 2.64$; $2.64 / 4 = .66146$ or 66.15%).

In Section Q, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

The applicant assumes that the number of in-center patients at Asheville Kidney Center will increase at 0.3 percent per year based on the Five-Year AACR for Buncombe County, as reported in Table D of the July 2019 SDR. The facility serves nine patients from other counties and assumes those patients will continue to dialyze at Asheville Kidney Center but does not project any increase in the number of out-of-county patients. The applicant projects that 39 Buncombe County in-center patients will transfer to Arden Dialysis upon the facility's certification.

Projected utilization is reasonable and adequately supported based on the following:

- The applicant begins its utilization projection with the existing Buncombe County patient census currently served at Asheville Kidney Center.
- The applicant projects the Buncombe County in-center patient census at Asheville Kidney Center will increase at the Buncombe County Five-Year AACR of 0.3 percent, as reported in the July 2019 SDR.
- The applicant projects the number of patients from other counties that are dialyzing at Asheville Kidney Center will remain constant.

In Section D, page 29, the applicant states:

“The transfer of stations from Asheville Kidney Center will have no effect on the ability of low-income persons, racial and ethnic minorities, women, handicapped persons, and other undeserved groups and the elderly to obtain needed health care.

...

Asheville Kidney Center by policy, will continue to make dialysis services available to all residents in its service area without qualifications.

...

Asheville Kidney Center will continue to assist uninsured/underinsured patients with identifying and applying for financial assistance...”

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- The needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

C

The applicant proposes a change of scope and cost overrun for Project ID# B-11037-15 (Develop a new dialysis facility by relocating 10 stations from Swannanoa Dialysis Center to Arden Dialysis) to relocate no more than 4 dialysis stations from Asheville Kidney Center to Arden Dialysis pursuant to Policy ESRD-2, for a total of no more than 14 stations upon completion of this project and Project ID# B-11037-15.

In Section E, page 30, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective to meet the need than the alternative proposed in this application. The alternatives considered were:

Maintain the Status Quo-The applicant states that this alternative was dismissed due to the need for additional capital cost for the development of Project ID# B-11037-15. In addition, the applicant states that this alternative would not address the need identified in Section C of this application.

Relocate Stations from Another DaVita Facility-The applicant states that the two DaVita facilities in Buncombe County are operating at less than 80% capacity. Relocating stations from Weaverville Dialysis would negatively impact the patients being served at the facility.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- Patients wanting to transfer their services to Arden Dialysis.
- The applicant proposed to develop the project as approved in Project ID# B-11037-15
- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Total Renal Care of North Carolina, LLC shall materially comply with the representations made in this application and the representations made in Project I.D. B-11037-15. Where representations conflict, Total Renal Care of North Carolina, LLC shall materially comply with the last made representation.**

2. Pursuant to Policy ESRD-2, Total Renal Care of North Carolina, LLC shall relocate four dialysis stations from Asheville Kidney Center to Arden Dialysis.
 3. Upon completion of this project, Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify four dialysis stations at Asheville Kidney Center for a total of no more than 48 dialysis stations at Asheville Kidney Center.
 4. Total Renal Care of North Carolina, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes a change of scope and cost overrun for Project ID# B-11037-15 (Develop a new dialysis facility by relocating 10 stations from Swannanoa Dialysis Center to Arden Dialysis) to relocate no more than 4 dialysis stations from Asheville Kidney Center to Arden Dialysis pursuant to Policy ESRD-2, for a total of no more than 14 stations upon completion of this project and Project ID# B-11037-15.

Capital and Working Capital Costs

This application includes a cost-overrun of \$641,681 which results in a total combined capital cost of \$1,914,206. In Section F, page 34, the applicant states that the cost overrun is due to the construction costs at the new site and the furniture, fixtures and equipment for the additional stations. In Exhibit C-9, the applicant provides a Material Compliance approval letter dated July 31, 2018 for the change of site for Project ID# B-11037-15.

The following table compares the previously approved capital cost and the proposed capital cost, as reported on Form F.1b in Section Q.

Arden Dialysis – Previously Approved and Proposed Capital Cost			
	Previously Approved Cost (B-11037-15)	Additional Costs Projected (B-11831-19)	Total
Site Preparation	\$125,000	107,707	(\$17,293)
Construction/Renovation Contract(s)	\$656,000	\$1,118,460	\$462,460
Architect/Engineering Fees	\$60,000	\$81,406	\$21,406
Medical Equipment	\$158,040	\$220,960	\$62,920
Non-Medical Equipment	\$151,788	\$258,760	\$106,972
Furniture	\$121,697	\$99,675	(\$22,022)
Interest During Construction	\$0	\$27,238	\$27,238
Total Capital Costs	\$1,272,525	\$1,914,206	\$641,681

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F, page 32, the applicant projects that start-up costs will be \$194,899 and initial operating expenses will be \$737,125 for a total working capital of \$932,024. In Project B-11037-15, the total working capital was \$900,433. On page 34, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F, page 31, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing		
Type	Total Renal Care of North Carolina, LLC	Total
Loans	\$	\$
Accumulated reserves or OE *	\$641,681	\$641,681
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing	\$	\$

* OE = Owner's Equity

In Section F, page 33, the applicant states that the working capital needs of the project will be funded, as shown in the table below.

Sources of Financing for Working Capital		Amount
(a)	Loans	\$
(b)	Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$932,024
(c)	Lines of credit	\$
(d)	Bonds	\$
(e)	Total *	\$932,024

Exhibit F-2 contains a letter from the Chief Accounting Officer for DaVita Inc., parent company to Total Renal Care of North Carolina, LLC, authorizing the use of accumulated reserves for the capital and working capital needs of the project. Exhibit F-6 contains a copy of the Consolidated Balance Sheets from DaVita, Inc., for years ending December 31, 2017 and December 31, 2018. DaVita, Inc. had adequate cash and assets to fund both the original capital cost for Project ID# B-11037-15 as well as the increase in capital costs proposed in this project.

Financial Feasibility

In Project ID #B-11037-15, the applicant projected revenues would exceed expenses in the first two operating years of the project. In this change of scope and cost overrun application, the applicant projects revenues will exceed expenses in the first two operating years of the project. The following tables show the revenue projections as presented in the first application and the revenue projections for the proposed project.

Projected Revenues and Operating Expenses (Project ID# B-11037-15)		
Arden Dialysis	Operating Year 1 CY18	Operating Year 2 CY19
Total Net Revenue	\$1,497,102	\$1,542,774
Total Operating Expenses (Costs)	\$1,438,690	\$1,472,267
Net Income/Profit	\$58,412	\$64,507

Projected Revenues and Operating Expenses (Project ID #B-11831-19)		
Arden Dialysis	Operating Year 1 CY21	Operating Year 2 CY22
Total Treatments	6,669	6,669
Total Gross Revenues (Charges)	\$2,189,948	\$2,189,948
Total Net Revenue	\$2,295,785	\$2,295,785
Average Net Revenue per Treatment	\$344	\$344
Total Operating Expenses (Costs)	\$1,474,250	\$1,492,679
Average Operating Expense per Treatment	\$221	\$224
Net Income/Profit	\$821,535	\$803,106

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the following:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

The applicant proposes a change of scope and cost overrun for Project ID# B-11037-15 (Develop a new dialysis facility by relocating 10 stations from Swannanoa Dialysis Center to Arden Dialysis) to relocate no more than 4 dialysis stations from Asheville Kidney Center to Arden Dialysis pursuant to Policy ESRD-2, for a total of no more than 14 stations upon completion of this project and Project ID# B-11037-15.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Thus, the service area is Buncombe County. Facilities may serve residents of counties not included in their service area.

Facility Name	Certified Stations as of 12/31/2018	# of In-center Patients as of 12/31/2018	Utilization by Percent as of 12/31/2018	Patients Per Station
Asheville Kidney Center	52	166	79.81%	3.1923
South Buncombe County Dialysis*	0	0	0.00%	0.0000
Swannanoa Dialysis Center	10	0	0.00%	0.0000
Weaverville Dialysis	20	54	67.50%	2.7000
Total	82	220		

Source: July 2019 SDR, Table B
 *Currently named Arden Dialysis

In Section G, page 37, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing dialysis services in Buncombe County.

“No new services are included in this proposal. As in the previously approved application, Arden Dialysis will offer in-center dialysis services. The scope of this project included an additional four stations to be relocated from Asheville Kidney Center for a total of 14 stations at Arden Dialysis.”

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The proposal will not duplicate existing services because the proposed stations will be relocated from an existing dialysis facility.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to approved additional dialysis stations.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section Q, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	As of 12/31/2018	2nd Full Fiscal Year CY22
Administrator	0	1.0
Register Nurse	0	2.0
Technicians (PCT)	0	6.0
Dietician	0	0.5
Social Worker	0	0.5
Admin./Business Office	0	0.5
Other-Biomedical Tech	0	0.3
TOTAL	0	11.0

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q.

Project ID# B-11037-15 adequately demonstrated the methods to be used to recruit new positions and its proposed training and continuing education programs.

The application for Project ID# B-11037-15 was found conforming to this criterion, and the applicant proposes no changes in the current application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

Project ID# B-11037-15 adequately demonstrated the availability of the ancillary and support services necessary to the provision of the proposed services and adequately demonstrated the proposed services would be coordinated with the existing healthcare system.

The application for Project ID# B-11037-15 was found conforming to this criterion, and the applicant proposes no changes in the current application which would affect that determination.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

A certificate of need was issued September 29, 2015 for Project B-11037-15, (Develop a new dialysis facility by relocating 10 stations from Swannanoa Dialysis Center to Arden Dialysis.) This applicant is change of scope to relocate four dialysis stations from Asheville Kidney Center to Arden Dialysis pursuant to Policy ESRD-2, for a total of no more than 14 stations upon completion of this project and Project ID# B-11037-15. This application includes a cost-overflow of \$641,681 which results in a total combined capital cost of \$1,914,206.

According to a Material Compliance Approval letter dated July 31, 2018, the applicant was approved to change the proposed location to 2625 Hendersonville Road, Arden, in Buncombe County. In the prior project, the applicant proposed to upfit 5,600 square feet. In this this application, the proposed project involves upfitting 6,260 square feet of leased space. In Exhibit K-5 the applicant provides updated line drawings that reflect the additional four dialysis stations proposed in this application. In Section Q, Form F.1a, the applicant adequately demonstrates the need for additional construction costs.

The application for Project ID# B-11037-15 was found conforming to this criterion, and the applicant proposes no other changes in the current application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the

State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Project B-11037-15, the applicant stated that the majority of the patients who will use the relocated facility reside in the Asheville area and dialyze at Asheville Kidney Center. In Section L, page 46, the applicant provides the historical payor mix for Asheville Kidney Center in-center patients during last Operating Year (CY2018) for the proposed services, as shown in the table below.

Payor Category	In-Center Dialysis	
	# of Patients	% of Total
Self-Pay	0.0	0.0%
Insurance**	13.9	8.4%
Medicare**	123.3	74.3%
Medicaid**	11.9	7.2%
Other (VA)	16.9	10.2%
Total	166.0	100.0%

Source: Section L, page 46
 **Including any manage care plans

In Section L, page 45, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full OY	Percentage of the Population of the Service Area
Female	37.2%	52.1%
Male	62.8%	47.9%
Unknown	0.0%	0.0%
64 and Younger	63.3%	80.0%
65 and Older	36.7%	20.0%
American Indian	0.0%	0.5%
Asian	2.0%	1.4%
Black or African-American	30.7%	6.3%
Native Hawaiian or Pacific Islander	2.0%	0.2%
White or Caucasian	57.3%	89.4%
Other Race	8.0%	2.2%
Declined / Unavailable		

*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 46, the applicant states they are not obligated to provide uncompensated care, community service or access by minorities and persons with disabilities.

In Section L, page 46, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Project B-11037-15, the applicant states that the majority of the patients who will use the relocated facility reside in the Asheville area and dialyze at Asheville Kidney Center. In Section L, page 47, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project based on payments received in the last operating year at Asheville Kidney Center, as shown in the table below.

Arden Dialysis Payor Category	In-Center Dialysis	
	# of Patients	% of Total
Self-Pay	0.0	0.0%
Insurance**	3.8	8.4%
Medicare**	33.4	74.3%
Medicaid**	3.2	7.2%
Other (VA)	4.6	10.2%
Total	45.0	100.0%

Source: Section L, page 46

**Including any manage care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that of 74.3% total services will be provided to Medicare patients and 7.2% to Medicaid patients.

On page 47, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the applicant based its projected payor mix on the sources of patient payments that have been received in the last full operating year by the facilities losing stations.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

The application for Project ID# B-11037-15 was found conforming to this criterion, and the applicant proposes no changes in the current application which would affect that determination.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

The application for Project ID# B-11037-15 was found conforming to this criterion, and the applicant proposes no changes in the current application which would affect that determination.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes a change of scope and cost overrun for Project ID# B-11037-15 (Develop a new dialysis facility by relocating 10 stations from Swannanoa Dialysis Center to Arden Dialysis) to relocate no more than 4 dialysis stations from Asheville Kidney Center to Arden Dialysis pursuant to Policy ESRD-2, for a total of no more than 14 stations upon completion of this project and Project ID# B-11037-15.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Buncombe County. Facilities may serve residents of counties not included in their service area.

Facility Name	Certified Stations as of 12/31/2018	# of In-center Patients as of 12/31/2018	Utilization by Percent as of 12/31/2018	Patients Per Station
Asheville Kidney Center	52	166	79.81%	3.1923
South Buncombe County Dialysis*	0	0	0.00%	0.0000
Swannanoa Dialysis Center	10	0	0.00%	0.0000
Weaverville Dialysis	20	54	67.50%	2.7000
Total	82	220		

Source: July 2019 SDR, Table B
 *Currently named Arden Dialysis

The applicant proposes a change of scope and a cost overrun for Project ID# B-11037-15. That application adequately demonstrated the expected effects of the proposed services on competition and how any enhanced competition would have a positive impact on cost-effectiveness, quality, and access to the services proposed. The applicant proposes no changes in this application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q, Form A, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 107 of this type of facility located in North Carolina.

In Section O, page 51, the applicant states that during the 18 months immediately preceding the submittal of the application, incidents of immediate jeopardy occurred in one of these facilities. The applicant states that the facility is now in compliance. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 107 DaVita facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- NA- The applicant is relocating stations from an existing facility.
- (b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- In Section Q, the applicant projects to serve 45 in-center patients in OY1. Thus, the applicant projects that Arden Dialysis will have a utilization rate of 80.4% or 3.214 patients per station per week ($45 \text{ patients} / 14 \text{ stations} = 3.214 / 4 = 0.8036$ or 80.4%) in OY1. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section Q, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.